

**510(k) Summary of Safety & Effectiveness, Continued**

<b>Indications for Use</b>	The Reprocessed Diagnostic Electrophysiology Catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.
<b>Contra-indications</b>	<ul style="list-style-type: none"> <li>• Patients with active systemic infection.</li> <li>• Patients with prosthetic valves.</li> <li>• Retrograde approach in patients with aortic valve replacement.</li> <li>• Transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle patch.</li> <li>• Patients with acute factors that make the findings unrepresentative of the patient's usual state (i.e. drug toxicity, electrolyte abnormality, acute ischemia).</li> <li>• Patients with underlying cardiac disease that increases risk of being unable to terminate induced arrhythmias and that have a high risk of death (i.e. unstable angina, acute myocardial infarction, hemodynamic instability).</li> <li>• Diagnostic EP catheters are not intended for electrical ablation.</li> </ul>
<b>Device Description</b>	<p>Vanguard reprocessed diagnostic electrophysiology catheters are constructed of a hollow polymer shaft 6 – 8 French in diameter and 110 cm in length that terminates with a hand piece. Various configurations of distal platinum alloy electrodes are wired to a proximal connector at the end of the hand piece for bi-directional transmission of electrical signals (pacing and recording). The proximal connector is attached to an interconnecting cable that interfaces with various standard types of sensing, recording, stimulation, and pacing equipment. The catheters are available with various steerable distal curves for remote manipulation of the distal tip segment to facilitate precise positioning of the electrode array. The catheters are also available in a variety of electrode configurations that are selected by the clinician based on preference and/or indication. The shaft polymer is manufactured with additives (typically barium sulfate) that enhance the catheter's radiopacity to enable positioning under fluoroscopic guidance. No lumens of the catheters reprocessed by Vanguard are open to the patient bloodstream.</p> <p>In clinical use, diagnostic electrophysiology catheters are placed under fluoroscopy within the heart, near major structures of the conduction system. The effects of pacing on the conduction system and time intervals between waveforms are recorded, measured, and compared to baseline and normal values. The electrocardiogram normally has atrial, His, and ventricular components in order to obtain accurate interval measurements which are used to establish the baseline and current status of the conduction system.</p>

*Continued on next page*

## 510(k) Summary of Safety & Effectiveness, Continued

---

<b>Technological Characteristics</b>	The Vanguard Reprocessed Diagnostic Electrophysiology Catheters are essentially identical to the currently marketed Original Equipment Manufacturer (OEM) devices. Device materials, specifications, and technological characteristics are equivalent.
<b>Test Data</b>	Cleaning, sterilization, and packaging validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.
<b>Conclusion</b>	Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that Vanguard Reprocessed Diagnostic Electrophysiology Catheters are substantially equivalent to their predicate devices under the Federal Food, Drug and Cosmetic Act.

---



JUN 1 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vanguard Medical Concepts, Inc.  
c/o Ms. Heather Crawford, RAC  
Director of Regulatory Affairs  
5307 Great Oak Drive  
Lakeland, FL 33815

Re: K050763

Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters  
(See Enclosed List)

Regulation Number: 21 CFR 870.1220

Regulation Name: Electrode Recording Catheter or Electrode Recording Probe

Regulatory Class: Class II

Product Code: NLH

Dated: March 23, 2005

Received: March 24, 2005

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Brad D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

List of Model numbers

<b>Models Found SE</b>
<b>Valve Mapper SteeroCath-Dx &amp; SteeroCath-Dx</b>
2001
2031L
2200
2270
2270K2
2270N4
2270L
2028BL
2027BL

## Indications for Use

510(k) Number (if known): K050763

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheter

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

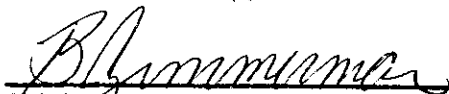
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K050763